REMARKS

Reconsideration of this application is respectfully requested.

Claims 146-163 are new. Applicants note that new claims 146-163 require that:

(1) the claimed mammal is a live-born clone,

(2) the clone is a clone of the donor mammal,

(3) the donor mammal is a non-embryonic, non-foetal mammal,

(4) the donor mammal exists prior to the clone, and

(5) the clone is younger than its parent by at least the foetal gestation time of the parental donor mammal.

Claims 146-163 are supported throughout the specification. For example, the specification states:

> The use of the invention is not restricted to a particular cell type. All cells of normal karyotype, including embryonic, foetal and adult somatic cells, which can be induced to enter quiescence or exist in a quiescent state in vivo may prove totipotent using this technology. . . . an ovine mammary epithelial cell derived cell line (OME) from a 6 year old adult sheep . . . are exemplified below. .

(Specification at 7, lines 15-19.)

Rejections under 35 U.S.C. § 101

Claims 128 and 145 were rejected under 35 U.S.C. § 101 because the claimed invention is allegedly directed to non-statutory subject matter. The Office contends that the claims lack evidence of the hand-of-man. The Office alleges that, since a clone is a copy of a previously known animal, the copy cannot be considered statutory subject matter. Applicants traverse the rejection.

New claims 146-163 recite a live-born clone of a pre-existing, non-embryonic, non-foetal, donor mammal. A clone of a pre-existing, non-embryonic, non-foetal, donor

mammal is never found in nature because the clone is produced asexually. Nature does not make copies of such mammals. The Office does not contest this point. Consequently, the hand-of-man is required for applicants' clone to exist. Although applicants' clone is a copy of a previously known animal, it is not the same mammal because it occupies a different space and time than the previously known animal. Accordingly, applicants respectfully request withdrawal of the rejection.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 128 and 145 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement for cloned primates. Applicants traverse the rejection.

Any conclusion regarding the cloning of primates must take into account the low efficiency of the cloning process. As noted in Pennisi and Vogel, "[f]irst and foremost is the problem of efficiency" (at 1722, col. 1, last ¶) and "Dolly was the product of 434 attempts at nuclear transfer, all but one of which went bad." (at 1723, col. 12, first ¶) With respect to primates, Pennisi and Vogel state that there have been "300 attempts and no pregnancies." (At 1726, col. 2, first ¶.) Based on these numbers, the known inefficiency of the cloning process can account for the lack of reported success in primates. Accordingly, the Office's conclusion that cloning in primates was unpredictable is in error.

In addition, applicants' new claims 146-163 recite that the mammal is selected from cattle, sheep, pigs, goats, mice, rabbits, horses, and rats. Thus, these claims obviate the rejection.

Claims 128 and 145 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The Office contends

that the specification does not contemplate a mammal and its clone together or a pair of mammals. The Office further alleges that there is no support for the terms "adult" and "parental."

Applicants traverse the rejection for the reasons set forth in the Amendment filed May 7, 2004. In addition, applicants' new claims 146-163 do not recite a mammal and its clone together, a pair of mammals, the term "adult," or the term "parental." Thus, these claims obviate the rejection.

Rejections under 35 U.S.C. § 112, second paragraph

Claim 145 was rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite in reciting the terms "parental" and "adult."

Applicants traverse the rejection. Applicants submit that that the skilled artisan would understand the meaning of claim 145. However, as discussed above, new claims 146-163 do not recite these terms, and thus the rejection is moot.

Rejections under 35 U.S.C. § 102(b)

Claim 145 was rejected under 35 U.S.C. § 102(b) as being anticipated by Sims et al., 1993. The Office contends that claim 145 does not require that the clone be a clone of the parent.

Applicants traverse the rejection. The clone in claim 145 must be a clone of the parent since the clone is ***its*** live offspring clone. In addition, new claims 146-159 make clear that the clone is of the donor mammal. Accordingly, this rejection is moot.

Claims 128 and 145 were rejected under 35 U.S.C. § 102(b) as being anticipated by Seike et al., 1993. The Office contends that Seike et al. discloses two calves

produced by embryo-splitting and that these calves could not be distinguished from applicants' mammals.

Applicants traverse the rejection. The calves in Seike et al. are missing a limitation of applicants' claims, namely, one of the calves is not a clone of a pre-existing, non-embryonic, non-foetal, donor mammal. Therefore, Seike et al. cannot anticipate applicants' claims, and applicants respectfully request withdrawal of the rejection.

Claims 128 and 145 were rejected under 35 U.S.C. § 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Morris et al., 1993. The Office contends that Morris et al. discloses a heifer that gave birth to two calves, and that the heifer and either of the two calves anticipate, respectively, the mammal from which a somatic cell has been taken and the clone of the mammal.

Applicants traverse the rejection. The heifer and either of the two calves in Morris et al. are missing a limitation of applicants' claims, namely, one of the calves is not a clone of a pre-existing, non-embryonic, non-foetal, donor mammal. Therefore, Morris et al., cannot anticipate applicants' claims, and applicants respectfully request withdrawal of the rejection.

Moreover, Morris et al, cannot make obvious applicants' claims. Nowhere does Morris et al. teach or suggest that one of the animals is a clone of a pre-existing, non-embryonic, non-foetal, donor mammal. None of the animals in Morris et al. is a clone. Thus, Morris et al. cannot make applicants' claims obvious, and applicants respectfully request withdrawal of the rejection.

Furthermore, a distinguishing feature of applicants' claimed mammals is that applicants' clone creates a situation that never existed prior to applicants' invention.

This situation involves the existence of a non-embryonic, non-foetal, donor mammal prior to the existence of a clone of that mammal. Thus, one is able to physically examine applicants' donor mammal prior to the generation of a clone of that mammal. The benefits of this situation are readily apparent and cannot be considered obvious from the animals found in the prior art.

The Examiner contends that it is not clear what applicants mean by the clone having "the same set of chromosomes" as the parental mammal. Applicants point out that a clone is an animal that is ***asexually*** reproduced. Thus, the parental donor and the progeny clone have the same set of chromosomes. This is quite different from normal sexual reproduction in which a progeny receives one half of its chromosomes from each of its parents. The calves of Morris et al. are sexually produced and are not clones of the heifer. Therefore, the calves do not have the same set of chromosomes as the heifer.

Prior to applicants' invention, no mammal existed that had the same set of chromosomes as (i.e., was a clone of) its parent. This is an unexpected property of applicants' clone. This property of applicants' clone allows one to distinguish between them and sexually produced mammals. (February 5, 2003, Declaration of David Wells at ¶¶5-35.) Thus, the Office is in error in asserting that "based on genome alone, the heifer and calves of Morris, and the claimed donor and clone or parent and clone, cannot be distinguished." (See Office Action at 10.)

Conclusion

Applicants respectfully submit that this application is now in condition for allowance. If the Examiner believes that issues remain to be addressed before a Notice

of Allowance, applicants respectfully request that the Examiner contact the undersigned to discuss any outstanding issues.

If there is any fee due in connection with the filing of this Amendment, please charge the fee to Deposit Account No. 06-0916.

Respectfully submitted,

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By: _____

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